For Method
Balloon works regardless of
perfusion lumen.

US-PAT-NO: 5116305

DOCUMENT-IDENTIFIER: US 5116305 A
See image for Certificate of Correction

TITLE: Curved intra aortic balloon with non-folding inflated
balloon membrane

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Brief Summary Text - BSTX (2):
The present invention relates to devices such as intra aortic balloon pumps (IABPs) wherein an inflatable envelope or balloon mounted on the end of a long catheter is inserted through a blood vessel to a position in the **aorta** where it is operated to supplement the cardiac pumping action.

Brief Summary Text - BSTX (4):
Insertion of the balloon to a site in the **aorta** is accomplished by first compacting the uninflated balloon, by folding, wrapping, twisting or the like, and then inserting the compacted balloon assembly through an artery using a guide wire and/or sheath to guide it past irregularities or branches in the artery. Care must be taken during insertion to avoid trauma or perforation, particularly when the balloon is passing branches or curves of the artery.

Brief Summary Text - BSTX (6):
When intra aortic balloons (IAB) as described in application Ser. No. 257,752 are inflated within the **aorta,** a pressure differential along the length of the balloon develops. As a result, the cardiac (forward) end of the balloon is exposed to a higher pressure than the opposite (tail)

end of the balloon.
This pressure differential may cause an undesirable folding in the tail end of
the balloon. The folding of the balloon reduces the lifetime and reliability
of the device as it adds stress to the balloon membrane and could eventually
lead to premature failure. It would be advantageous to provide an IAB which
would exhibit a relatively long operational life.

Drawing Description Text - DRTX (2):
FIG. 1 is a perspective view of an inflated catheter balloon of the
invention positioned within the ascending **aorta**.

Detailed Description Text - DETX (4):
FIG. 1 generally illustrates the application of an intra aortic balloon
(IAB) device 10 of the present invention in which a catheter balloon 12 having
an inflatable balloon membrane is positioned in an inflated condition within
the ascending **aorta** 14.

Detailed Description Text - DETX (9):
As noted above, the balloon 12 is cylindroidal, having a curved, generally
elongate structure. In the inflated condition, shown in FIG. 1, the balloon
has maximum diameter transverse to its longitudinal axis at a plane 38,
somewhat behind the midpoint of the balloon along the balloon's longitudinal
axis. From its end 24 proximal to the heart, the inflated balloon increases in
diameter to its maximum diameter 38. The diameter of the balloon then
decreases from point 38 to the distal end 40 of the balloon. The balloon at
distal end 40 tapers such that the end of inflating catheter 16 fits within and
is secured to the balloon. When the balloon is inflated, its largest diameter
is sufficient to occlude the **aorta**. The wall thickness of

the balloon membrane 13 typically is approximately 3-5 mils, however, the membrane may feature reinforced areas of increased thickness which may be from about 1.2 to 1.6 times thicker than the remainder of the wall.

Detailed Description Text - DETX (13):

As noted earlier, lumen 22 preferably is a hollow lumen used to monitor pressure and to sample fluids on the cardiac side of the **balloon**. Alternatively, lumen 22 may be a solid or hollow member which simply provides support and assists in maintaining **balloon** curvature. In either case, lumen 22 may be manufactured of a polymeric material, such as **polyurethane**, by known extrusion techniques. Exemplary **polyurethane** materials from which lumen 22 may be manufactured include those sold by Dow Chemical Company under the trade name "Isoplast 101". In other embodiments member 22 may consist of a spiral wound wire tube or the like. Catheter 16, like lumen (or member) 22, may also be formed of similar **polyurethane** materials, using known extrusion techniques.

Detailed Description Text - DETX (14):

The **balloon** typically is manufactured by dip coating a mandrel with a polymeric material such as **polyurethane**. Preferred **polyurethanes** include "Texin", available from Mobay Chemical company; "Avcothene - 51", available from Kontron Cardiovascular, Inc. "Angioflex" available from Abiomed, Inc., and "Biomer" available from Ethicon, Inc. In a preferred embodiment the volumetric compliance of the **balloon** membrane is about 5 to 15 cc/100 mm Hg transmembrane pressure. The preferred **diameter** compliance of the **balloon** membrane ranges from about 2-5 **mm**/100 **mm** Hg transmembrane

pressure. These
compliance values are based upon a **balloon** having a nominal volume of 45 cc.
Compliance values are expected to change relative to changes in the nominal
volume of the **balloon**.

Claims Text - CLTX (1):
1. A cardiac assist device for insertion into the **aorta,** comprising:

Claims Text - CLTX (3):
a catheter means for providing fluid to the balloon when the balloon is
positioned within the **aorta,** said catheter means being joined at a terminal end
thereof to one end of the balloon; and

Claims Text - CLTX (20):
17. The device of claim 1 wherein the balloon is formed of a thin
elastomeric material, said balloon having a **diameter** compliance in the range of
about 2-5 **mm**/100 mmHg transmembrane pressure.

Claims Text - CLTX (21):
18. A cardiac assist device for insertion into the **aorta,** comprising:

Claims Text - CLTX (23):
a catheter means for providing fluid to the balloon when the balloon is
positioned within the **aorta,** said catheter means being joined at a terminal end
thereof to one end of the balloon; and

Claims Text - CLTX (33):
22. A cardiac assist device for insertion into the **aorta,** comprising:

$\frac{2\ mm}{100\ mmHg} \times \frac{100\ mmHg}{1.93367\ psi} = \frac{1\ mm/ps}{2.0\ mm/psi}$

100 mmHg = 1.9 psi

Claims Text - CLTX (35):
a catheter means for providing fluid to the balloon when the balloon is positioned within the **aorta,** said catheter means being joined at a terminal end thereof to one end of the balloon;

Claims Text - CLTX (38):
23. A cardiac assist device for insertion into the **aorta,** comprising:

Claims Text - CLTX (40):
a catheter means for providing fluid to the balloon when the balloon is positioned within the **aorta,** said catheter means being joined at a terminal end thereof to one end of the balloon; and

Other Reference Publication - OREF (2):
Abstract Entitled "Effectiveness of A Counter Pulsation Device Implanted on the Ascending **Aorta** vs. Intra-Aortic Balloon Pump in Sever Cardiogenic Shock".

Other Reference Publication - OREF (5):
Brown et al.--"Improved Intraaortic Balloon Diastolic Augmentation with a Double-Balloon Catheter in the Ascending and the Descending Thoracic **Aorta**".